

Preparing for BioShield

*Secretary's Advisory Council on
Public Health Preparedness*

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Project BioShield

BioShield was announced by President Bush in his State of the Union address on January 28, 2003.



The DHS appropriations bill (PL 108-90) signed by President Bush on 1 October 2003 provided **\$890 million in discretionary funds in FY2004 and created a discretionary reserve of \$5.6 billion to fund the program through FY2013.**

Funding is available for countermeasures once production of licensable products is judged scientifically feasible. **HHS will be the procuring authority.**

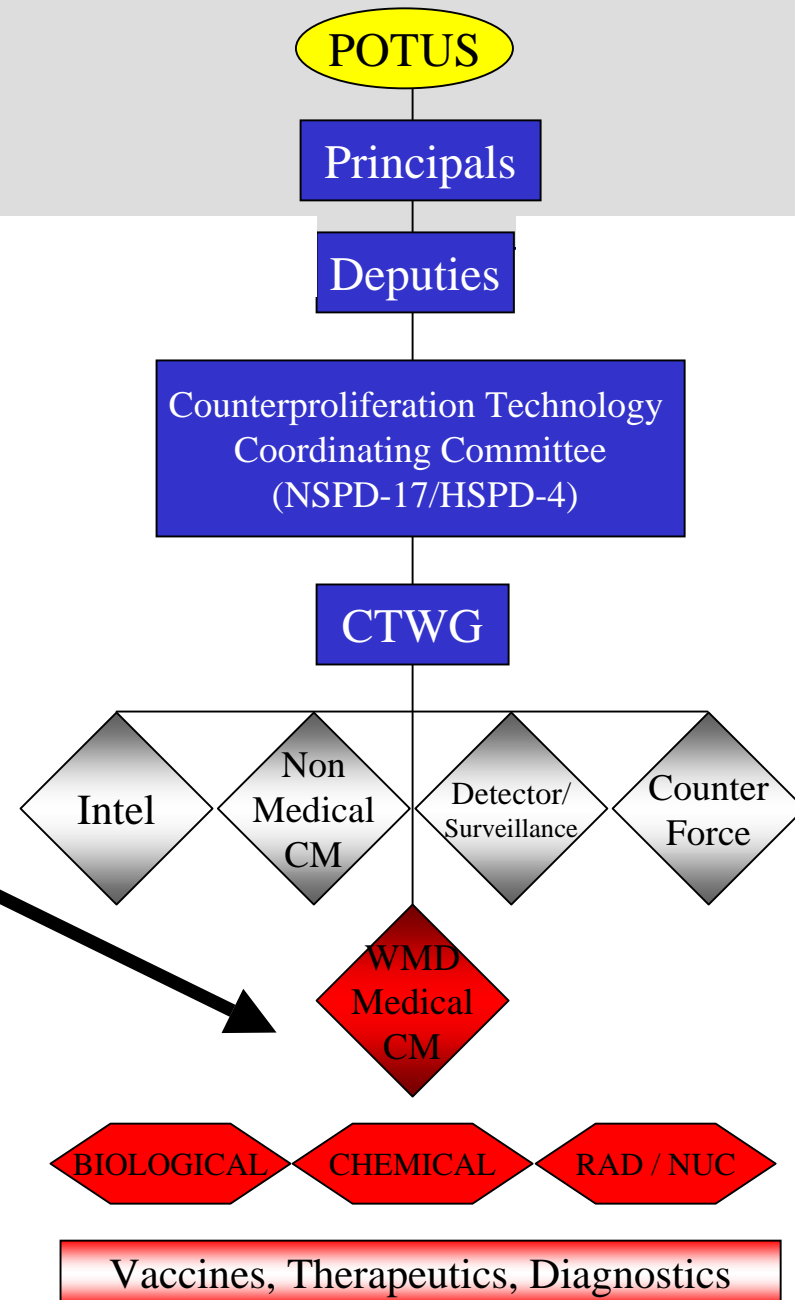
WMD Medical Countermeasures Committee

- Prioritize federal initiatives
 - Address immediate and long-term needs
 - Recommend national requirements for vaccines, drugs, antitoxins, diagnostics
 - Represent needs of civilian and military
- Coordinate research, development, and acquisition efforts of key federal agencies: HHS, DHS, and DoD
- Accelerate development of critical products



HHS has a leadership role in the WMD Medical Countermeasures Committee

This Committee will coordinate national requirements, acquisition strategies, and requests for Project BioShield funding



Interagency Coordination

- Weapons of Mass Destruction Medical Countermeasures Committee
 - Analyzes requirements
 - Reviews Acquisition Strategy
 - Develops and presents options for specific acquisitions a Policy Coordinating Committee (Asst. Sec. level) and to Deputies Committee



Release of BioShield Funds

- Interagency determination of the requirement
- Findings by Secretaries of DHS and HHS
 - Determination of material threat - DHS
 - Determination that countermeasures are necessary. Determination that the security countermeasure is appropriate for inclusion in the stockpile – HHS
- Coordination with OMB and joint recommendation to President
- Approval by the President



White House photo by Paul Morse

Potential BioShield Procurements Under Consideration

- rPA anthrax vaccine
- Next generation smallpox vaccine
- Botulinum antitoxin (Equine)
- Anthrax immune globulin products
- Recombinant plague vaccine
- Botulinum vaccine
- Anti-radiation drugs and Chemical antidotes



Potential Future Candidates for BioShield Procurement

- Ebola-Marburg vaccine
- Rift Valley Fever Vaccine
- Novel antibiotic/antifolate
- Novel antiviral
- Human anthrax and botulinum antitoxins from transgenic animals
- 3rd Generation anthrax vaccine



Features of the HHS Next Generation (rPA) Anthrax Vaccine Program

- **Early Development** - Open competitive solicitation
 - September 30, 2002 two NIH contracts worth **\$22.5** million awarded to VaxGen (California) and Avecia (UK)
 - 12 mo. to complete 5 milestones through Phase 1
- **Advanced Development** - Open competitive solicitation
 - September 30, 2003 two contracts worth **\$151** were awarded to VaxGen and Avecia
 - 3 years to complete 17 milestones through manufacturing scale-up, Phase 2 trials, pre/post exposure animal models
- **BioShield Acquisition** – anticipated in 2004



rPA Vaccine Development – 2003 Highlights

- Milestones completed or in progress under existing contracts
 - cGMP manufacture of clinical trial lots
 - IND approval
 - Phase 1 clinical trials
 - Animal efficacy studies
 - Feasibility plans for manufacture and delivery of 25 million doses
 - Preclinical, Clinical and Regulatory Plans to support product licensure



Acquisition of rPA Anthrax Vaccine

- RFI issued August 03 to collect information about large-scale manufacturing capacity
- We anticipate that initial delivery of IND product to the Strategic National Stockpile is possible by late 2004



Anthrax Countermeasures – Next Steps

- Acquisition of an immune-based anthrax countermeasures for treatment of symptomatic patients
- Next generation anthrax vaccine with improved delivery systems
 - In Dec 2003, HHS sponsored a conference, “Innovative Administration Systems for Vaccines,” to provide a forum to facilitate the development of vaccine delivery systems that will enable rapid implementation of mass vaccination programs



Safer Smallpox Vaccine

- NIH funded R&D program for MVA progressing well
 - Two contracts awarded in February 2003
 - Bavarian Nordic
 - Acambis
 - Phase 1 and non-human primate studies
- NIH Advanced Development award(s) for MVA in mid-late 2004
- VaxGen independently developing LC16m8



Botulinum Antitoxin (Equine)

- Contract with Cangene for process development and processing of equine plasma from the military program
- Two contracts initiated for immunization of horses and collection of plasma
- Acquisition contract for processing plasma planned for late 2004, early 2005

